K082138

510(k) Summary

PerfAction's Airgent™ JAN 23 2009

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

PerfAction, Ltd
4 Pekeris Street,
Rehovot 7670211
Israel
Phone +972-8-9363004
Facsimile +972-8-9471540

Contact Person. Dalia Givony, VP Regulatory & Clinical Affairs

Date Prepared July 28, 2008

Name of Device and Name/Address of Sponsor

Airgent™
PerfAction, Inc
4 Pekeris Street,
Rehovot 7670211
Israel

Common or Usual Name Airgent™

Model Airgent™ US

Classification Name/Product Code/CFR Reference
Nonelectrically powered fluid injector

Product Code KZE, 21 C F R § 880 5430

Device Class

Class II

Classification Panel

General Hospital

Predicate Devices

Bioject 2000 (Bioject Inc , K960373)
Jet Syringe (Equidyne Systems, Inc , K003741)

Injex 30 (Equidyne Systems, Inc , K022148)

Intended Use/Indications for Use

The Airgent™ System is a needle-free injection system designed for the administration of various medicines and vaccines to the body by means of a high velocity jet of fluid that penetrates the skin The Airgent™ includes a disposable delivery kit intended for multiple injections on a single patient The Airgent™ System is indicated for professional use only"

Device Description

The Airgent™ System is an automated, multi-use, needless injector system, intended to deliver medications and vaccines to the body by a highly accelerated pneumatically powered jet of fluid via a very small entry point in the surface of the skin The system is comprised of a console and single-use sterile injector kit
The user may control the dosage (150µl/200µl) and system pressure for the injection via the graphical user interface on the front panel of the console
The entire injector kit is replaced between patients and may be used for multiple injections per patient

Performance Data

The Airgent performance and safety was tested in accordance with ISO 21649 -Needle-free Injectors for Medical Use Requirements and Test Methods

Comparison Testing
The equivalency test was performed to demonstrate that Airgent™ is as safe and effective as its predicates Specifically, ex-vivo testing was conducted to confirm the performance of Airgent The testing results demonstrated that the Airgent is as safe and effective as its predicate devices and in all instances, the Airgent functioned as intended

Substantial Equivalence

The Airgent System is as safe and effective as the Biojector, Jet Syringe and Injex 30 It has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices The minor technological differences between the Airgent and its predicate devices raise no new issues of safety or effectiveness Performance data demonstrate that the Airgent is as safe and effective as the Injex 30 Thus, the Airgent System is substantially equivalent to the identified predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2009

PerfAction, Incorporated
C/O Mr Jonathan S. Kahan
Hogan & Hartson L L P
555 Thirteen Street, North West
Washington, DC 20004

Re K082138
Trade/Device Name Airgent™
Regulation Number: 21 CFR 880 5430
Regulation Name. Nonelectrically Powered Fluid Injector
Regulatory Class II
Product Code KZE
Dated. January 16, 2009
Received January 16, 2009

Dear Mr Kahan

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www fda gov/cdrh/industry/support/index.html

Sincerely yours,

Anthony D. Watson for
Ginette Y. Michaud, M. D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K082138

Device Name Airgent™

Indications for Use:

The Airgent™ System is a needle-free injection system designed for the administration of various medicines and vaccines to the body by means of a high velocity jet of fluid that penetrates the skin The Airgent™ includes a disposable delivery kit intended for multiple injections on a single patient The Airgent™ System is indicated for professional use only

Prescription Use __X__ (Part 21 C F R 801 Subpart D)

AND/OR

Over-The-Counter Use____ (21 C.F R 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K082138